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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/782,899	02/23/2004	Minoru Fujimori	12381-002-999	5937
20583	7590	10/19/2009	EXAMINER	
JONES DAY 222 EAST 41ST ST NEW YORK, NY 10017			LONG, SCOTT	
			ART UNIT	PAPER NUMBER
			1633	
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			10/19/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

DETAILED ACTION

The examiner acknowledges receipt of Applicant's Remarks, filed on 6 July 2009.

Priority

This application claims benefit as a Continuation of U.S. Application No. 09/816,391 filed 26 March 2001 (abandoned). The instant application also claims benefit from foreign application JAPAN 2000-287688 filed 12 September 2000. Therefore, the application has been granted the benefit date, 12 September 2000 from the foreign application, JAPAN 2000-287688.

Information Disclosure Statement

The new Information Disclosure Statements (IDS) filed on 6 July 2009 consisting of 1 sheet is in compliance with 37 CFR 1.97. Accordingly, examiner has considered the Information Disclosure Statements.

RESPONSE TO ARGUMENTS

35 USC § 103

The rejection of claims 47-51 and 58-64 under 35 U.S.C. 103(a) as being unpatentable over Yazawa et al. (Proceedings of the American Association for Cancer

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Research Annual Meeting, Vol. 40, pp. 88, 1999) in view of Brown et al.

(US2003/0103952) and further in view of Goshima et al. (Biochimie, 1990. vol.72: 207-214) and further in view of Claret et al. (J. Mol. Biol. 1997; 273: 93-104) is withdrawn in response to the applicants arguments.

The applicant's arguments have been fully considered and are persuasive. The applicant has argued (1) the HU gene is not a housekeeping gene which is constitutively, as suggested by the examiner in previous actions; (2) the promoter activity of *B. longum* HU protein is not predictable from understanding the *E. coli* HU-1 and HU-2 protein promoters, as suggested by the examiner in previous actions; (3) the cited art does not teach that the HU promoter is highly expressed, as suggested by the examiner in previous actions; (4) Goshima is silent on the use of *Bifidobacterium* HU promoter and a skilled artisan would not choose this promoter based upon the teachings of Goshima. The examiner and his supervisor were persuaded by these arguments when presented during the interview of 6/15/2009. In total, the examiner is convinced that a skilled artisan, based on what was known in the art, would not have chosen to use the *Bifidobacterium longum* HU promoter to express an antitumor substance in a *Bifidobacterium longum* gene therapy vector.

Therefore, the examiner hereby withdraws the rejection of claims 47-51 and 58-64 under 35 U.S.C. 103(a) as being unpatentable over Yazawa et al. in view of Brown et al. and further in view of Goshima et al. and further in view of Claret et al.

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CLAIM OBJECTIONS

The objection to claim 53-57 and 73-79 as being dependent upon a rejected base claim is withdrawn in response to the allowability of the independent claim.

NEW GROUNDS OF REJECTION

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 47-51, 53-64, and 73-79 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 7 and 17-20 of copending Application No. 11/718680. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the instant

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claims and the claims of the copending application encompass *Bifidobacterium* bacteria comprising a vector having the HU promoter and terminator which expresses a protein having antitumor activity.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

CONCLUSION

No claims allowed.

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Examiner Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Scott Long** whose telephone number is **571-272-9048**. The examiner can normally be reached on Monday - Friday, 9am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Joseph Woitach** can be reached on **571-272-0739**. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Scott Long/
Patent Examiner, Art Unit 1633